The contradictory approach of the CJEU to the judicial review of standards: a love-hate relationship?

5. The Contradictory Approach of the CJEU to the Judicial Review of Standards: A Love–Hate Relationship?[1]

Annalisa Volpato and Mariolina Eliantonio

Odi et amo. Quare id faciam fortasse requiris.
nescio, sed fieri sentio et excrucior.

I hate and I love. Why do I do this, perhaps you ask.
I do not know, but I feel it happening and I am tortured.
(Catullus, Carmina, Poem 85)

1. INTRODUCTION

In a globalised and increasingly complex world, the role of technical standards in different policy fields is inevitably growing. Originating from the initiative of private players and organisations, standards are often used by public authorities in the regulation of important economic sectors, thus progressively blurring the line between public and private domains.[2] As a consequence of this increasing use of technical standards in public regulation, standards penetrate the legal orders in a variety of ways, both at the national and the EU level.

In particular, standards enter the EU legal system through various legal mechanisms. Although these mechanisms often represent well-established instruments in the legal traditions of Member States, they are far from being

[1] The work elaborates on a common interest of the authors. Annalisa Volpato wrote Sections 2 and 3.2, and Mariolina Eliantonio authored Sections 1 and 3.1. Section 4 is the outcome of the authors' joint effort.

[2] Gunther Teubner, 'Global Private Regimes: Neo-Spontaneous Law and Dual Constitution of Autonomous Sector?' in Karl-Heinz Ladeur (ed), *Public Governance of the Age of Globalization* (Ashgate 2004) 71–87; Hanneke van Schooten and Jonathan Verschuuren (eds), *International Governance and Law: State Regulation and Non-State Law* (Edward Elgar 2008); Lorenzo Casini, '"Down the Rabbit Hole": The Projection of the Public/Private Distinction beyond the State' (2014) International Journal of Constitutional Law 12: 402–28.

unproblematic. Indeed, the specific legal mechanism may affect the position of standards vis-à-vis the EU legal system and, consequently, the possibility of the judicial review of standards before the Court of Justice of the European Union (CJEU).

The question of accountability of private or hybrid global regulatory regimes is not a new one and has been considered by scholars who deal with the emergence and development of global administrative law.[3] That scholarship has indeed observed that 'domestic systems of administrative accountability through law are being increasingly side stepped'[4] by global regulatory mechanisms, such as standard-setting processes, producing 'norms' which are subsequently implemented at the national level.

However, most of the scholarship has concentrated on the applicability of general principles of due process (such as transparency and participation in decision-making) to global regulatory regimes.[5] The scholarship which has

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[3] Benedict Kingsbury and Richard B Stewart, 'Legitimacy and Accountability in Global Regulatory Governance: The Emerging Global Administrative Law and the Design and Operation of Administrative Tribunals of International Organizations' in Spyridon Flogaitis (ed), *International Administrative Tribunals in a Changing World* (Esperia 2008); and generally on global administrative law see for example Benedict Kingsbury, Nico Krisch and Richard B Stewart, 'The Emergence of Global Administrative Law' (2004) Law and Contemporary Problems, Issue 3, 68: 15–61; Sabino Cassese, 'Administrative Law Without the State? The Challenge of Global Regulation' (2005) NYU Journal of International Law and Politics 37(5): 663–94; Daniel C Esty, 'Good Governance at the Supranational Scale: Globalizing Administrative Law' (2006) The Yale Law Journal 115: 1490–1562; Lorenzo Casini, 'Beyond Drip-painting? Ten Years of GAL and the Emergence of a Global Administration' (2015) International Journal of Constitutional Law 13(2): 473–7; Anthony Gordon, Jean-Bernard Auby, John Morison and Tom Zwart, *Values in Global Administrative Law* (Hart Publishing 2011); Lorenzo Casini, 'The Expansion of the Material Scope of Global Law' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 25–44; Stefano Battini, 'The Proliferation of Global Regulatory Regimes' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 45–64; Fabrizio Cafaggi, 'Transnational Private Regulation: Regulating Global Private Regulators' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 212–41.

[4] Richard B Stewart, 'The Global Regulatory Challenge to U.S. Administrative Law' (2005) New York University Journal of International Law and Policy 37: 695.

[5] For example Lorenzo Casini, 'Global Hybrid Public–Private Bodies: The World Anti-Doping Agency (WADA)' (2009) International Organisations Law Review, Issue 2, 6: 421–46; Sabino Cassese, 'Global Standards National Administrative Procedures' (2005) Law and Contemporary Problems, Issue 3, 68: 109; Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) European Journal of International Law 17(1): 187–214; Stefano Battini, 'The Procedural Side of Legal Globalization: The Case of the World Heritage Convention' (2011) International Journal of Constitutional Law, Issue 2, 9: 340; Marco Macchia, 'The

examined the judicial side of the production of norms at the global level has focused on the existence and effectiveness of international courts,[6] thereby neglecting the question of judicial supervision and judicial review of standards at the domestic level.

The question of the availability of judicial review is one which strikes at the core of the inner struggle of global and hybrid regulatory regimes: the quest for efficiency while preserving the basic tenets of the rule of law.[7] Indeed, 'the institutional bedrock of most rule of law models lies in judicial review as an independent review of the legality of administrative action'.[8] The availability of judicial review, in turn, would be able to enhance the legitimacy of the standardisation process as a regulatory technique since it would guarantee an *ex post* control of the activities of the standard-setting bodies. From this perspective, one could argue that judicial review would contribute both to 'the internal legitimacy of an organization that can plausibly claim to adhere to its own rules, but also to its external legitimacy, in that it would be open to impartial control'.[9] Also, the availability of judicial review could serve to compensate for the shortcomings identified with respect to the transparency and representativeness of various standard-setting bodies, by adding an additional layer of control.[10]

Rule of Law and Transparency in the Global Space' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 261–81; Simon Chestennan, 'Globalization Rules: Accountability, Power, and the Prospects for Global Administrative Law' (2008) Global Governance, Issue 1, 14: 39.

6 See for example Mikael R Madsen, 'Judicial Globalization: The Proliferation of International Courts' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 282–302; Elisa D'Alterio, 'Judicial Regulation in the Global Space', in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 303–24. See also Barbara Marchetti, 'The Enforcement of Global Decisions' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 242–60, who, however, considers the *enforcement* rather than the *review* of global norms at the domestic level.

7 Christoph Möllers, 'Constitutional Foundations of Global Administration' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 107–30.

8 Ibid, 113.

9 Ibid. Further on this Joseph HH Weiler, 'The Rule of Lawyers and the Ethos of Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement' (2001) Journal of World Trade, Issue 2, 35: 191.

10 See for example with regard to the Codex Alimentarius, Alexia Herwig, 'The Contribution of Global Administrative Law to the Legitimacy of the Codex Alimentarius Commission' in Olaf Dilling, Martin Herberg and Gerd Winter (eds), *Transnational Administrative Rule-Making* (Hart Publishing 2011). See also in general for this issue concerning the networks of regulators, Paul Craig, 'Global Networks and Shared Administration' in Sabino Cassese (ed), *Research Handbook of Global*

Furthermore, the availability of judicial review of standards would increase the so-called throughput legitimacy of this phenomenon. While input legitimacy relates to the responsiveness to citizens' concerns as a result of participation by the people,[11] throughput legitimacy is judged in terms of efficacy, accountability and transparency. Despite the fact that 'standard-setting requires not only scientific knowledge, but also subjective policy decisions about the level of risk a society is willing to accept',[12] the input legitimacy of the standardisation process is considered to be remarkably low.[13] In light of this, judicial review as a tenet of throughput legitimacy in its specific dimension of accountability could compensate for the low performance of the standardisation process in terms of input legitimacy.

Against the backdrop of the importance of judicial review for the legitimacy of the standard-setting procedures, and the lack of research on this topic,[14] this chapter aims to fill this academic gap by examining the different ways in which standards enter the EU legal order. Discussing the role and legal value of standards in the EU legal system is essential not only for the purposes of determining the current possibilities of judicially reviewing them, but also, normatively, in order to establish to what extent the standards *ought to be* reviewable in the first place. If indeed the purpose of judicial review

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Administrative Law (Edward Elgar 2016) 153–74 and the seminal work by Anne-Marie Slaughter, *A New World Order* (Princeton University Press 2004).

[11] Vivien A Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and "Throughput"' (2013) Political Studies, Issue 1, 61: 2–22.

[12] Lori M Wallach, 'Accountable Governance in the Era of Globalization: The WTO, NAFTA and the International Harmonization of Standards' (2002) University of Kansas Law Review, Issue 4, 50: 863.

[13] See for example Nicholas Hachez and Jan Wouters, 'A Glimpse at The Democratic Legitimacy of Private Standards – Assessing the Public Accountability of Global G.A.P.' (2011) Journal of International Economic Law 14(3): 677–710; Morten Kallestrup, 'Stakeholder Participation in European Standardization: A Mapping and an Assessment of Three Categories of Regulation' (2017) Legal Issues of Economic Integration 44(4): 381–94; Sabrina Wirtz, *The Interplay of Global Standards and EU Pharmaceutical Regulation* (PhD thesis 2017) 207–32.

[14] See however the recent works done on judicial review of the European standardisation process, for instance Mariolina Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) Legal Issues of Economic Integration 44(4): 399–404; Carlo Tovo, 'Judicial Review of Harmonised Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) Common Market Law Review, Issue 4, 55: 1187–1216; Annalisa Volpato, 'The Harmonized Standards before the ECJ: James Elliott Construction' (2017) Common Market Law Review 54: 591–604; Mariolina Eliantonio and Carlo Colombo, 'Harmonized Technical Standards as Part of EU Law: Juridification with a Number of Unresolved Legitimacy Concerns?' (2017) Maastricht Journal of European and Comparative Law 24(2): 323–40.

is to support the realisation of the rule of law and enhance the legitimacy of standardisation as a regulatory technique, given the variety of standard-setting processes, and the ensuing variety of modalities in which standards become part of EU law, the answer to the normative quest for judicial review cannot be monolithic. In this respect, relevant criteria to be taken into account are

> the hierarchical status of the rule in question, its dependence on further political decisions, the formal possibility to deviate from it, and the existence of procedural possibilities to revise it. The more entrenched, directly applicable and hierarchically supreme the norm, the more urgent is its lack of legitimacy. The more exposed is the rule to independent review and to political procedures of exemption and alteration, the less demanding are the expectations for a legitimate rule-making procedure[15]

The consequent need for judicial review is a further relevant criterion.

This contribution will first examine different legal mechanisms by which standards enter the EU legal system and then focus on the issues relating to the judicial review of standards and the effective protection of the individuals' rights affected.

2. ENTERING THE EU LEGAL ORDER: HOW STANDARDS PIERCE THE EU LAW VEIL

2.1 The Incorporation of Private Standards by Reference

In an overview of the ways in which standards enter the EU legal system,[16] the first mechanism to consider is undoubtedly the reference to private standards in EU legislation. Indeed, the EU legislator may introduce in its acts provisions which do not directly regulate the matter, but refer to rules established by standardisation bodies, thus indirectly granting a regulation for the relevant activities. Such references may be contained in legislative acts,[17] or non-legislative acts;[18] they may concern standards elaborated by bodies

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[15] Möllers, above n. 7, 123.

[16] See in general on the incorporation of norms produced at the global level in the national legal systems and the incentives for their incorporation, Richard B Stewart, 'Global Standards for National Societies' in Sabino Cassese (ed), *Research Handbook of Global Administrative Law* (Edward Elgar 2016) 175–98.

[17] See, for instance, Articles 7 and 8 of Regulation (EC) 648/2004 of the European Parliament and of the Council on detergents [2004] OJ L104, 1–35 (referring to ISO standards on tests for surfactants and good laboratories practices). See also the Annexes of the same Regulation.

[18] See, for instance, Commission Implementing Decision (EU) 2017/1358 on the identification of ICT Technical Specifications for referencing in public procurement [2017] OJ L190, 16–19 (referring to technical specifications of 3WC, OASIS, Internet

established in connection to international law treaties,[19] or by purely private organisations.[20]

In this regard, the most straightforward example is the Commission measures through which references to CEN/CENELEC standards are published in the Official Journal pursuant to the corresponding New Approach directives or regulations.[21] Indeed, the New Approach consists precisely in regulating through legislative acts only the 'essential requirements' of general interest of a product, while delegating the detailed definition of technical aspects to these private organisations composed of experts and representatives of the business sector.[22] The following publication by the Commission endows these technical standards with the legal nature of 'harmonised European standards' and provides a presumption of conformity with the secondary law measures they are aimed at complementing. As recently recognised by the Court, the result of this mechanism is that the harmonised standards are to be considered as 'part of EU law',[23] being incorporated by reference into the EU legal system.

Although the New Approach represents a highly idiosyncratic system which raises peculiar questions in terms of legitimacy,[24] incorporation by reference

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Engineering Task Force and Internet Engineering Task Force, all private standardisation bodies).

[19] Such as the Universal Postal Union, which was established by the Treaty of Bern of 1874 and is composed of 192 member countries. Its standards are referred to in Articles 226 and 227 of Regulation (EU) 952/2013 of the European Parliament and of the Council laying down the Union Customs Code [2013] OJ L269, 1–101.

[20] Such as the abovementioned 3WC (World Wide Web Consortium) which is composed of private companies, NGOs, research institutes and universities.

[21] On the New Approach, see *inter alia* Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005); Jacques Pelkmans, 'The New Approach to Technical Harmonisation and Standardisation' (1987) Journal of Common Market Studies 25(3): 249–69. On the recent shift in the Commission's practice, see para 3.1.

[22] See Commission of the European Communities, *Completing the Internal Market: White Paper from the Commission to the European Council,* Milan, 28–29 June 1985, COM(85)310 final; Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards, [1985] OJ C136/1; Council Resolution of 21 December 1989 on a global approach to conformity assessment, [1990] OJ C10/1; Regulation (EU) 1025/2012 of the European Parliament and of the Council on European standardisation, [2012] OJ L316/12.

[23] See Case C-613/14, *James Elliott Construction Limited v Irish Asphalt Limited* EU:C:2016:821, para 40. See also C-185/17, *Mitnitsa Varna v SAKSA* EU:C:2018:108.

[24] See, *inter alia*, Christian Joerges, Harm Schepel and Ellen Vos, The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Processes: The Case of Standardisation under the New Approach, EUI Working Paper No 99/9 (1999); Ernesto Previdi, 'The Organisation of Public and Private Responsibilities in European Risk Regulation: An Institutional Gap between Them?'

does not constitute an entirely new technique in law. In fact, references to rules established by other legal systems, and even by private organisations,[25] are quite common in national law. In this context, constitutional law scholars have elaborated the fundamental distinction between 'static' references, which are directed to specific acts or provisions, and 'dynamic' references, which concern the legal source of the acts in its decision-making activities. While the static reference entails the incorporation of the provision referred to as it is at the moment of reference, the dynamic reference comprises the subsequent modifications of the rule enacted by that source, thus allowing the evolution of the normative provisions deriving from that source to be taken into account.[26]

While such a distinction was expressly elaborated in relation to national legal systems, EU law arguably also presents examples of these variants of reference. Thus, on the one hand, for instance, Article 2 of Directive 2016/802 refers to a precise method elaborated by ASTM International, a US-based standardisation body.[27] This kind of reference allows the interpreter to clearly identify and apply the relevant rule with the content intended by the EU legislator, thus granting legal certainty with regard to the status of the rule in the relevant legal system. On the other hand, a dynamic reference, such as Article 226 of the Union Custom Code referring to 'the acts of the Universal Postal Union',[28] permits the constant adaptation of the legal framework to normative and technical progress without the need to amend the EU measure. In this

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in Christian Joerges, *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos 1997) 225–42; Linda Senden, 'The Constitutional Fit of European Standardization Put to the Test' (2017) Legal Issues of Economic Integration 44(4): 337–52; Megi Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) Legal Issues of Economic Integration 44(4): 353–66; Tovo, above n. 14, 1187–1216; Eliantonio and Colombo, above n. 14, 323–40.

[25] See, *inter alia*, the US case *State v Crawford*, [1919] Kansas 177, cited also in Maurizia De Bellis, 'Public Law and Private Regulators in the Global Legal Space' (2011) International Journal of Constitutional Law 9(2): 425–48.

[26] For the notion of fixed and dynamic reference in Italian literature, see, *inter alia*, Vezio Crisafulli, *Lezioni di diritto costituzionale* (Cedam 1970); Livio Paladin, *Le fonti del diritto italiano* (Il Mulino 1993); Roberto Bin and Giovanni Pitruzzella, *Diritto co-stituzionale* (Giappichelli 2003).

[27] Specifically, the ASTM D86 method. See Article 2 of Directive (EU) 2016/802 of the European Parliament and of the Council relating to a reduction in the sulphur content of certain liquid fuels [2016] OJ L132, 58–78.

[28] Other examples of dynamic referral may be found in Article 7 of Regulation (EC) 648/2004 of the European Parliament and of the Council on detergents [2004] OJ L104, 1–35; Annex II of Regulation (EC) 661/2009 of the European Parliament and of the Council concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor [2009] OJ L200, 1–24; Annex I of Directive 2009/125/EC of the European

sense, despite its problematic implications, the dynamic referral provides more flexibility and efficiency in rule-making, rendering this a valuable instrument in the hands of the legislator.[29]

While the distinction is clear in the abstract, the concrete qualification of a reference as a static or dynamic may give rise to certain doubts in specific cases. An example emerges from the legal framework for the approval of vehicles in the EU. Directive 2007/46/EC establishes a framework for the approval of motor vehicles and their trailers,[30] and makes extensive reference to the UNECE Regulations as alternative and equivalent rules applicable for this approval.[31] In this regard, in 1958 the EU decided to accede to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles (the so-called Revised 1958 Agreement). The international standards and regulations adopted within this framework at the time of EU accession are considered 'incorporated within the Community type-approval procedure either as requirements for EC vehicle type-approval, or as alternatives to existing Community law'.[32] In order to avoid a duplication of regulation at EU and international level, these regulations are simply referred to in the Annexes of the Framework Directive without reproducing them in the directive or in its implementing measures.[33] Although the recitals may suggest that this is a typical case of dynamic reference, Article 35(2) of the Framework Directive makes it clear that the subsequent modifications are not automatically incorporated in EU law, but require an express decision of the Council. In the case of new UNECE regulations or amendments, the Council may decide to adopt them and the Commission is empowered to amend the relevant parts of the Annex to the Framework Directive.[34] Therefore, considering that an act of

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Parliament and of the Council establishing a framework for the setting of ecodesign requirements for energy-related products [2009] OJ L285, 10–35.

29 De Bellis, above n. 25, 428.

30 Directive 2007/46/EC of the European Parliament and of the Council establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) [2007] OJ L263, 1–160.

31 Articles 34 and 35 of the Framework Directive.

32 Recital 11 of the Framework Directive. In particular, the UNECE Amendments listed in Part I of Annex IV are part of the EC type-approval of a vehicle in the same way as the separate directives or regulations, whereas those listed in Part II of the same Annex are recognised as being equivalent to the corresponding separate directives or regulations.

33 As recommended by Recital 12 of the Framework Directive.

34 Recital 11 and Article 35(2) of the Framework Directive. See Diego Zannoni, 'Balancing Market Needs and Environmental Protection: Vehicle Approval in the

an EU institution, albeit at a subordinate level of the Framework Directive, is needed, arguably this qualifies the referring provisions as static references.

2.2 The Incorporation of Private Standards by Reproduction

In addition to the legal mechanism of reference, standards also penetrate the EU legal order in other – somewhat more subtle – ways. Notably, international standards are sometimes incorporated in EU measures, reproducing verbatim the wording of the relevant standards and, thus, becoming part of EU law. The origin of the rules as international standards may be more or less evident and this kind of incorporation may involve binding or non-binding acts.

Among the international standards incorporated as non-binding EU law are the standards elaborated by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), an international standardisation body bringing together the regulatory authorities of different countries and the pharmaceutical industry.[35] The standards of this organisation, which is the leading global standard-setter for pharmaceuticals, are often adopted as guidelines by the European Medicines Agency (EMA).[36]

The incorporation of international standards in EU law may be demanded by international obligations which bind the EU under international law. For instance, in the context of the WTO agreements, the SPS and TBT agreements expressly require the Member States to use the international standards as 'a basis for their technical regulations'.[37] While this obligation was initially interpreted as requiring that the Member State 'adopt[s] some, not necessarily all, of the elements of the international standard',[38] in the *Sardines* case the WTO Appellate Body clarified that a 'very strong and very close relationship' is needed to consider a national rule as based on an international standard.[39]

This obligation is qualified by the possibility for the Member States to introduce or maintain national rules which provide a higher level of sanitary or phytosanitary protection,[40] or which are necessary to fulfil a legitimate objec-

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European Union' (2018) Maastricht Journal of European and Comparative Law 25(4): 500–15.

35 For a detailed analysis, see the contribution by Sabrina Wirtz in this book.

36 Remarkably, 19 per cent of the European Medicines Agency guidelines originate in the ICH. See Wirtz, above n. 13, 273.

37 Article 2.4 TBT Agreement. See also Article 3.1 SPS Agreement.

38 Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones),* WT/DS26/AB7R, WT/DS48/AB/R) 16 January 1998, para 76.

39 Appellate Body, *European Communities – Trade Description of Sardines,* (WT/DS231/AB/R) 23 October 2002, para 245.

40 Article 3.3 SPS Agreement.

tive.[41] However, in this case specific procedural duties apply,[42] such as a notice and comment procedure.[43] Furthermore, national rules mirroring the relevant international standards enjoy a presumption of conformity with the obligations under the WTO agreements, particularly useful in case of litigation before the WTO Dispute Resolution Boards, thus providing remarkable incentives for the incorporation of these standards.[44]

For these reasons, Article 13 of Regulation 178/2002 laying down the general principles and requirements of food law includes an obligation for the EU and its Member States to 'promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced'.[45] Accordingly, EU food law is often drafted on the basis of the standards elaborated by the *Codex Alimentarius* Commission,[46] an international body expressly mentioned along with the International Office of Epizootics (IOE) and the International Plant Protection Convention (IPPC) in the SPS Agreement. Thus, through the drafting of EU law in accordance with the outputs of these international standardisation bodies, international standards affecting the health and safety of human, animal and plant life are incorporated in EU measures.[47]

Even more complex is the way international standards elaborated in relation to the TBT Agreement enter the EU legal order. In this regard, it is interesting

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[41] Legitimate objectives are, *inter alia*, national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. See Article 2.2 TBT Agreement.

[42] Under Article 3.3 SPS Agreement, the Member State must also provide a scientific justification for the measure.

[43] Article 2.5 and 2.9 TBT Agreement. See also De Bellis, above n. 25, 437.

[44] Article 2.5 TBT Agreement and Article 3.2 SPS Agreement. See also De Bellis, above n. 25, 437.

[45] Article 13(e) of Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31, 1–24.

[46] The Codex Alimentarius Commission, established in 1961 under the auspices of the FAO and the WTO, is composed of the representatives of 189 States plus the EU. It meets once a year with the aim of developing and updating international standards and guidelines to protect the health of consumers and to ensure fair practices in the international food trade. Although the Member States were already members of this organisation, the EU has formally acceded the Codex with Council Decision 2003/822/CE. See, *inter alia*, Luigi Costato, *Compendio di diritto alimentare* (Cedam 2015) 37–9.

[47] See, for instance, Directive 2012/12/EU of the European Parliament and of the Council amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption [2012] OJ L115, 1–11, adopted to take account of developments in the Codex General Standard for fruit juices and nectars (Codex Stan 247-2005).

to note that, although the TBT Agreement does not mention explicitly the relevant standardisation bodies, they can easily be identified as the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC).[48] With the view to removing the international obstacles to trade and promoting the interoperability of products,[49] whenever possible the standards elaborated by these organisations constitute the basis for the elaboration of European standards by CEN and CENELEC.[50] When foreseen in the relevant legislative acts, thus, they become part of EU law through the reference in the Official Journal.

3. THE JUDICIAL REVIEW OF STANDARDS

The incorporation of international and European standards into the EU legal order arguably implies that, in accordance with the rule of law,[51] these standards are required to be subject to sufficient judicial control by the CJEU, notwithstanding the fact that the rules find their origin outside the EU legal system. As recently argued by Advocate General Bobek, the incorporation of an originally external legal act into EU law cannot result in 'black holes' of judicial review, which would arise if the standards were shielded from a judicial control by the mere fact of being originally drafted by a third party.[52]

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[48] De Bellis, above n. 25, 436.

[49] The European Standardisation Bodies are members of the ISO and take part in the elaboration of these international standards. Although the ISO statute does not require the members to adopt the international standards (see Article 4.2 of ISO Statutes), in 1991 the CEN has stipulated an agreement for technical cooperation with the ISO (the so-called Vienna agreement) with the aim of preventing duplication of standards, which recognises the primacy of international standards and promotes the 'adoption of existing international standards as European standards' (see Article 4 of the Vienna agreement). See also the IEC–CENELEC Agreement on common planning of new work and parallel voting, signed in Frankfurt in 2016.

[50] See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'European Standards for the 21st Century', COM(2016) 358, 2. In particular, in 2017, 33 per cent of the CEN catalogue was identical or based on the ISO deliverables, whereas 72 per cent of the CENELEC catalogue was identical or based on the IEC deliverables (see Global Outreach Report Q4 2017, available at www.cencenelec.eu).

[51] For the definition of the EU as a 'Community based on the rule of law', see Case 294/83 *Les Verts v Parliament* EU:C:1986:166, para 23.

[52] See Opinion of Advocate General Bobek in Case C-587/15 *Lietuvos Respublikos transporto priemonių draudikų biuras v Gintaras Dockevičius and Jurgita Dockevičienė* EU:C:2017:234, para 88: 'Once an EU institution decides to incorporate an originally external legal act into EU law and to draw legal consequences from it by effectively enforcing it internally … the same institution cannot later turn a blind eye and suggest that since that act was originally drafted by a third party, it is therefore not an act of that

However, the use of the specific legal mechanism of the reference raises two issues which are well known in private international law: the possibility to review the legality of the applicable rules and the problem of the legal framework against which the legality of these rules can be assessed.[53]

3.1 The Jurisdiction of the Court of Justice of the European Union on Standards

The problem arises in different terms for standards produced by European standardisation organisations according to the New Approach (or standards produced at the global level by an international standardisation organisation and which later become harmonised European standards), and global standards which are referred to or reproduced into EU binding or non-binding legislation.

First, it is by now established, following the *James Elliott* case,[54] that a harmonised European standard can be reviewed by the European courts in preliminary questions of interpretation,[55] as well as of validity,[56] under Article 267 TFEU. This is because a harmonised European standard, elaborated by an organisation governed by private law, is considered to form part of EU law 'when that standard was conceived, managed and monitored by the Commission, and when it produces binding legal effects following publication of its references in the Official Journal'.[57] Rather surprisingly, however, even when all these conditions are met, not all the elements of a harmonised European standard necessarily become part of EU law. In the *Mitnitsa* case, the Court considered a harmonised European standard drawn up by CEN on the basis of a Commission request not to form part of EU law with regard to the specific part of the standard that was not related to the reference made in the relevant legislative act.[58]

Even less clear is whether harmonised European standards can be subject to a direct action under Article 263 TFEU. Contrary to the opinion of the

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institution. Allowing for such "black holes" of judicial review would be incompatible with the vision of a Union based on the rule of law.'

[53] See, *inter alia*, Bruno Barel and Stefano Armellini, *Diritto Internazionale Privato* (Giuffré 2016) 71–8; Tito Ballarino, Eleonora Ballarino and Ilaria Pretelli, *Diritto internazionale privato italiano* (Cedam 2013).

[54] Case C-613/14 *James Elliott Construction Limited v Irish Asphalt Limited* EU:C:2016:821.

[55] This stems directly from the *James Elliott* case, para 34.

[56] See Toolbox #18 'The Choice of Policy Instrument', attached to the latest Better Regulation package. https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-18_en_0.pdf.

[57] Case C-185/17, *Mitnitsa Varna v SAKSA* EU:C:2018:108, para 39.

[58] Ibid, para 42.

Advocate General in the case,[59] in *James Elliott* the Court refused to consider them as 'acts of EU institutions, bodies, offices or agencies of the Union'.[60] Therefore, even without considering the issues related to the *locus standi* of private individuals in such direct actions,[61] the possibility of challenging a harmonised European standard under Article 263 TFEU remains controversial. An alternative to the direct action against a harmonised standard is the possibility of challenging the act of the Commission containing the reference to the standard,[62] and then raising the issue of the legality of the harmonised European standard before the Court.[63] In this regard, the recent shift in the practice of the Commission – which now publishes the reference to harmonised European standards in the L series of the Official Journal in the form of an Implementing Decision,[64] instead of in the C series as a Communication – is remarkable. Arguably, this shift opens up a clearer avenue for reviewing harmonised standards, since the 'reviewable act' nature of this decision to publish the reference can no longer be called into question.[65]

Second, in the case of globally produced standards, one would have to make a further differentiation between global standards which later become harmonised European standards, for which the considerations above should apply, and global standards which are instead referred to or reproduced into binding or non-binding secondary legislation. In the case of incorporation of global standards by reproduction into EU legislation, it could be argued that

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[59] Advocate General Campos Sánchez-Bordona in Case C-631/14 *James Elliott Construction Limited v Irish Asphalt Limited* EU:C:2016:63, para 40.

[60] Case C-613/14 *James Elliott Construction Limited v Irish Asphalt Limited* EU:C:2016:821, para 34. See, *inter alia*, Volpato, above n. 14, 600–1.

[61] Eliantonio, above n. 14, 399–404.

[62] Such a possibility was presented as admissible by the Court as early as Case T-474/15 *Global Garden Products Italy SpA v European Commission* ECLI:EU:T:2017:36, para 60. In literature, see *inter alia* Harm Schepel, 'The New Approach to the New Approach: The Juridification of Harmonised Standards in EU Law' (2013) Maastricht Journal of European and Comparative Law 20(4): 531.

[63] See, by analogy, the case law on the preparatory measures: Joined cases 12/64 and 29/64, *Ley v Commission*, EU:C:1965:28, para 118; Joined cases T-10-12 and 15/92, *Cimenteries and others v Commission*, EU:T:1992:123, para 31; Case T-123/03, *Pfizer v Commission*, EU:T:2004:167, para 24; Case T-108/92, *Calò v Commission*, EU:T:1994:22, para 13.

[64] See the publication of Commission Implementing Decision (EU) 2018/2048 of 20 December 2018 on the harmonised standard for websites and mobile applications drafted in support of Directive (EU) 2016/2102 of the European Parliament and of the Council, OJ L327 of 21 December 2018, 84–6.

[65] See Annalisa Volpato and Mariolina Eliantonio, 'The Butterfly Effect of Publishing References to Harmonised Standards in the L Series' europeanlawblog.eu (7 March 2019).

there should be no hurdles to the 'knowability' of these standards by the Court, as these standards are copied and pasted into EU measures, becoming indistinguishable from EU acts.[66]

However, a recent case concerning the so-called Green Card system, and in particular an international certificate attesting that the driver is insured against civil liability for any accident that may occur in the 'host country' adopted and administered by the Council of Bureaux, an international non-profit association established under Belgian law, would seem to cast doubts on this conclusion.[67] In this case, the global standard was incorporated by reproduction in an Annex to a Commission Decision, the interpretation of which was requested by a national court under Article 267 TFEU. The Advocate General in his opinion referred to *James Elliot* and concluded that

> in *Elliott*, the Court confirmed its jurisdiction to interpret a harmonised standard adopted by CEN (an organisation governed by private law) which had been published in the C series of the Official Journal. The Court noted that such a standard forms part of EU law, even more so if compliance with such standards is being enforced by the Commission. If such a conclusion holds for a technical standard published as a mere *communication* in the C series of the Official Journal, I am bound to conclude that the same must also apply, a fortiori, to that part of the Commission's decision published in the Official Journal as *binding legislation* in the L series of the Official Journal. Moreover, as already stated above, there are enforceable obligations flowing from that decision, likely to be enforced by the Commission.[68]

Yet the Court reached the opposite conclusion and without mentioning *James Elliott* simply stated that it did not have jurisdiction to interpret the private global norms because they 'were drawn up and concluded by bodies governed by private law without any institution, body, office or agency of the European Union participating in their conclusion'.[69] If the Court refused to *interpret* this global norm, it is even less likely that it would accept jurisdiction to review the *validity* of a globally produced standard even if it is reproduced into EU secondary law. In other words, this judgment calls for some caution with regard to the scope which the Court of Justice would set for its own jurisdiction to interpret globally produced standards which are reproduced into EU secondary legislation. The criterion emerging from this judgment – referring to the

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[66] Röttger-Wirtz, above n. 13, 273.

[67] Case C-587/15 *Lietuvos Respublikos transporto priemonių draudikų biuras v Gintaras Dockevičius and Jurgita Dockevičienė* ECLI:EU:C:2017:463.

[68] Opinion of Advocate General Bobek in Case C-587/15 *Lietuvos Respublikos transporto priemonių draudikų biuras v Gintaras Dockevičius and Jurgita Dockevičienė* EU:C:2017:234, paras 85–86.

[69] Para 39.

involvement of EU institutions in the standard-setting activities – appears to be far from convincing, leaving open questions on the extent and the effectiveness needed for this involvement to establish the Court's jurisdiction on these global standards.[70]

Third, the same conclusion should *a fortiori* apply to global standards which are 'merely' referred to in EU legislation. However, a case concerning the challenge to a piece of EU binding secondary legislation which referred to a global standard produced by the International Organisation of Vine and Wine (an intergovernmental body, OIV in the French acronym), seems to show another inconsistency of the Court in its scrutiny of standards. When discussing the legal value and force of the standards produced by the OIV, the Court stated that the standards clearly have 'legal effects' and were 'capable of decisively influencing the content of the legislation adopted by the EU legislature',[71] since the legal framework provided that the Commission was to 'base itself' on these standards when authorising oenological practices. This statement and the recognition of legal value of global standards in the EU legal system seems to be at odds with the Court's refusal to recognise its own jurisdiction on the interpretation (and *a fortiori* the validity) of the same standards.

3.2 The Legal Framework for Assessment

If the jurisdiction of the European courts on at least some of the standards applicable at the EU level is not certain, even more problematic is the question of the frame of reference according to which a standard would be judged.

In general, it could be argued that the first benchmark to assess their legality should be the same provision containing the reference to the standard. Indeed, while making the standard part of EU law, it may establish the limits and the conditions for this incorporation of the standard into the EU legal system.[72] For the particular case of harmonised standards, moreover, the Court clarified in *Anstar* that such standards must be interpreted in the light of the request from which they originate, which thus defines the limits for their interpretation and validity.[73] Furthermore, Regulation 1025/2012 defines specific principles and procedures for their adoption, making the acquisition of the presumption of

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[70] For instance, in relation to the standard elaborated by ICH, it is questionable whether the participation of officials from the European Commission and/or EMA is sufficient to fulfil this criterion.

[71] C-399/12, *Germany v Council* ECLI:EU:C:2014:2258, para 63.

[72] See Case C-185/17, *Mitnitsa Varna v SAKSA* EU:C:2018:108, para 42.

[73] C-630/16, *Anstar Oy v Tukes* EU:C:2017:971, paras 35–36.

conformity dependent on respect for these rules.[74] Therefore, in the case of harmonised European standards (including those originating at global level), the frame of reference is constituted not only by the essential requirements established in the relevant New Approach directive, but also by the request of the Commission and the provisions of Regulation 1025/2021.

However, it is less clear whether general principles of European administrative law, such as the principles of transparency and participation enshrined in Article 11 TFEU, apply to the European standardisation process, since harmonised European standards still remain acts of private organisations and not acts of EU institutions.[75]

The question becomes even more complex in the case of global standards, which originate from a different legal order and are 'only' incorporated into EU law. Indeed, it is questionable whether the elaboration of technical standards which are destined to be incorporated in EU law needs to abide by EU law, more precisely by the principles and rules of European administrative law. In other words, the question is whether the incorporation of the standards in the EU legal system in the ways analysed determines the application of the legal framework pertinent to the exercise of public power under EU law, or rather whether their legality shall be assessed according to the parameters and principles of their specific system. In this regard, it is interesting to recall that, in private international law, the use of the specific legal mechanism of the reference entails that the specific provision referred to shall be assessed under the parameters and with the methods of its own legal system.[76] Therefore, in the case of reference to standards elaborated by external standardisation bodies, the specific legal framework for assessing the legality of the standards ought not to be EU administrative law principles,[77] but rather the rules and proce-

[74] See Article 10(6) of Regulation (EU) 1025/2012 of the European Parliament and of the Council on European Standardisation [2012] OJ L316, 12–33.

[75] See further, Mariolina Eliantonio, 'Private Actors, Public Authorities and the Relevance of Public Law in the Process of European Standardization' (2018) European Public Law 24(3): 473–90.

[76] In this sense, the reference is directed not to the single rule, but to the legal system in its 'globality'. See, *inter alia*, Barel and Armellini, above n. 53, 77. *Contra* Ballarino, Ballarino and Pretelli, above n. 53.

[77] For a discussion of the qualification of European standardisation bodies as part of EU administration and, consequently, the possibility of applying administrative law principles to standardisation, see Matteo Gnes, 'Do Administrative Law Principles Apply to European Standardisation: Agencification or Privatisation?' (2017) Legal Issues of Economic Integration, Issue 4, 44: 367–80.

dures established by the same standardisation bodies in their self-regulation capacity.[78]

It is important, however, to recall also that such an approach in private international law is generally tempered by the application of limits guaranteeing the respect of the fundamental values of the legal system.[79] By analogy, it is arguable that the Court of Justice, when deciding on the validity of a standard incorporated in EU law, cannot refrain from ensuring respect of the democratic principles and the rule of law, which constitute the foundations of the EU legal order. The use of the specific legal mechanism of the reference, arguably, cannot justify a diminished protection of such fundamental principles, which are thus to be taken into account in the assessment of the legality of the standards, even where the standards enter the EU legal order through a reference.

In this respect, the Kadi saga, concerning the legality of EC Regulations that had implemented UN Security Council resolutions that listed and imposed sanctions on individuals suspected of involvement in international terrorism, is instructive. Indeed, in *Kadi I* the General Court argued that a global norm cannot be reviewed against EU law, as the EU acts under review were only implementing decisions taken by the UN: since the EU did not enjoy any discretion concerning the possible course of action, those EU decisions taken in implementation of UN decisions could not be reviewed against the fundamental principles of EU law.[80] However, in *Kadi II*, the Court of Justice moved away from this model of separation between legal orders and concluded that UN decisions cannot escape the respect of EU fundamental rights.[81] Applying this ruling to the standardisation process, it could be argued that the incorporation of standards elaborated by international organisations or standardisation

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[78] An example is the TBT Committee's Decision 'Principles for the Development of International Standards, Guides and Recommendations' (G/TBT/9) 13 November 2000. See De Bellis, above n. 25, 428.

[79] Reference here is, for instance, to the application of the limit of the public order and rules of necessary application in Italian system of private international law. See Article 16 of Italian Law 218/1995.

[80] Case T-85/09 *Yassin Abdullah Kadi v European Commission* ECLI:EU:T:2010:418.

[81] Joined cases C-402/05 and 415/05P *Kadi & Al Barakaat International Foundation v Council & Commission* ECLI:EU:C:2008:461. For a comment see Grainne de Búrca, 'The European Court of Justice, and the International Legal Order' (2009) Harvard International Law Journal 5(1) 1–53; Giacinto Della Cananea, 'International Security and Due Process of Law between the United Nations and the European Union: Yassin Abdullah Kadi & Al Baqaraat International Foundation v Council' (2009) Columbia Journal of European Law, Issue 3, 15: 511.

bodies in EU law implies that their elaboration shall live up to the procedural requirements granting the respect of fundamental rights protection in the EU.[82]

4. CONCLUSIONS

In the light of the inconsistent approach of the Court, it appears that, in spite of the increasing success of the use of standards as effective tools for public regulation in a variety of policy areas, many issues remain to be settled in relation to the accountability of private or hybrid regulatory regimes and, essentially, to the legitimacy of standard-making processes.

As shown above, standards penetrate the EU legal system in a variety of ways. In particular, standards may be incorporated into EU law through the legal mechanism of the reference, or through the reproduction of their text in EU acts, in binding or non-binding measures. The legal mechanisms according to which the standards enter the legal system influence the position of these standards under EU law and, consequently, their judicial review. Arguably, this affects not only the scope of the jurisdiction of the Court, but also the legal framework according to which the legality of incorporated standards should be assessed. However, if indeed, as proposed in the introduction, the purpose of judicial review is to support the realisation of the rule of law and, thereby, to enhance the legitimacy of standardisation as a regulatory technique, the position of the Court towards the judicial review of standards seems to run counter to the quest for the legitimacy of the standard-making process.

If looked through the lenses of criteria such as the hierarchical status of a standard and the formal possibility of deviating from it,[83] the attitude of the Court of Justice appears rather contradictory. On the one hand, the judicial review of harmonised European standards, which are formally not binding, has evolved in the sense of accepting the jurisdiction of the Court for their interpretation under Article 267 TFEU and, in light of recent developments, it seems more and more likely that they might be controlled in a direct action under Article 263 TFEU. On the other hand, this same possibility for other kinds of standards appears to still be precluded, even when incorporated by reproduction in EU law and thus constituting binding secondary EU law.

Even more problematic appears to be the lack of guidance with regard to the frame of reference according to which a standard would be assessed. In this regard, it is argued that the specific legal framework for assessing the legality of the standards ought not to be EU administrative law principles, but rather the rules and procedures established by the same standardisation bodies in

[82] See Röttger-Wirtz, above n. 13, 244.
[83] Möllers, above n. 7, 123.

their self-regulation capacity. However, such an approach should be mitigated by the respect of the democratic principles and the rule of law, assuring the respect for the fundamental rights guaranteed in the EU legal system. In this sense, further elaboration in case law and the literature is needed in order to determine more clearly the minimum guarantees of democracy and respect for the rule of law which standard-setting organisations should develop in order for their standards to be incorporated in EU law.

Such developments appear very necessary in the light of the uncertain legitimacy of standardisation in the EU legal system and, in particular, of the inconsistency of the Court on the issues related to the judicial review of standards. Much like Catullus' poem, it seems that the CJEU is currently in a love–hate relationship with standardisation. Why does the court do this, one could perhaps ask, to paraphrase the Latin poet. To continue with the paraphrasing: we do not know, but we feel (and see) it happening and the rule of law is tortured.